NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

METACEL PHARMACEUTICALS LLC,
Plaintiff-Appellant

v.

RUBICON RESEARCH PRIVATE LTD.,
Defendant-Appellee

2023-2386

Appeal from the United States District Court for the District of New Jersey in No. 2:21-cv-19463-EP-JRA, Judge Evelyn Padin.

Decided: April 23, 2025

MATTHEW ZAPADKA, Arnall Golden Gregory LLP, Washington, DC, argued for plaintiff-appellant. Also represented by KEVIN M. BELL.

TIMOTHY H. KRATZ, Kratz & Barry LLP, Atlanta, GA, argued for defendant-appellee. Also represented by GEORGE BARRY, III; MICHAEL PATRICK HOGAN, Philadelphia, PA; R TOUHEY MYER, Wilmington, DE.

Before LOURIE, CHEN, and HUGHES, *Circuit Judges*.

LOURIE, *Circuit Judge*.

Metacel Pharmaceuticals LLC ("Metacel") appeals from a final judgment of the United States District Court for the District of New Jersey granting summary judgment of no infringement of U.S. Patent 10,610,502 ("the '502 patent") in favor of Rubicon Research Private Ltd. ("Rubicon"). *See Metacel Pharms. LLC v. Rubicon Rsch. Priv. Ltd.*, No. 21-cv-19463, 2023 WL 5939903 (D.N.J. Sept. 12, 2023) ("*Reconsideration Decision*"); *Metacel Pharms. LLC v. Rubicon Rsch. Priv. Ltd.*, No. 21-cv-19463 (D.N.J. July 6, 2023) ("*Summary Judgment Decision*"), J.A. 6010–19.[1] For the following reasons, we affirm.

BACKGROUND

Metacel holds the FDA-approved New Drug Application ("NDA") 208193 for an oral solution of baclofen at a dosage strength of 5 mg/5 mL, which is sold under the brand name Ozobax®.[2] Ozobax is indicated for the

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[1] The *Summary Judgment Decision* is presently sealed under a confidentiality order of the district court. However, at oral argument, counsel for Rubicon indicated that the confidentiality order is no longer necessary since Rubicon's product is now on the market. *See* Oral Arg. 0:26–0:47, *available at* https://oralarguments.cafc.uscourts.gov/default.aspx?fl=23-2386_04082025.mp3 (counsel for Rubicon explaining that because "the Rubicon product is now on the market" and "everything is unredacted," the court is free to openly discuss the contents of its label). We therefore cite the *Summary Judgment Opinion* and corresponding exhibits directly where applicable.

[2] Metacel's 5 mg/5 mL dosage strength version of Ozobax is no longer being marketed in the United States and is currently listed in the discontinued section of FDA's Orange Book.

treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity. Metacel's sole Orange Book listing is the '502 patent, which Metacel describes there as a method of treating spasticity. The claims of the '502 patent are directed to a method of treating a known condition (*i.e.*, muscle spasms) with an old compound (*i.e.*, baclofen), and, as relevant here, are distinguished from the prior art by simply reciting an oral solution formulation stored according to a particular temperature condition. The '502 patent contains two claims. Independent claim 1 recites:

> 1. A method of relaxing muscles or treating spasticity in a subject in need thereof comprising administering to the subject an effective amount of an aqueous oral solution comprising (i) baclofen, (ii) a buffer comprising citric acid, a salt of citric acid, or any combination thereof, and (iii) optionally one or more preservatives, wherein . . . the oral solution is *stored . . . at from about 2 to about 8° C.*

'502 patent col. 10 ll. 48–59 (emphasis added). The issues on appeal relate solely to claim 1's refrigerated storage condition limitation, *i.e.*, storage "at from about 2 to about 8° C." *Id.* at col. 10 ll. 57–59.

Rubicon holds the now-approved Abbreviated New Drug Application ("ANDA") 214445 to market and sell a generic version of the 5 mg/5 mL formulation of Ozobax. As part of its ANDA submission, Rubicon included a proposed container label and package insert, both of which included the following storage instruction for its product:

> Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature]. *It can also be stored at 2°C to 8°C (36°F to 46°F).*

J.A. 603 (proposed container label) (emphasis added); J.A. 623 (package insert).[3] Rubicon also provided a paragraph IV certification with its ANDA, certifying, in part, that Metacel's '502 patent would not be infringed by the use or sale of Rubicon's product as described in its ANDA and subsequently provided Metacel with the required notice of that certification.[4] J.A. 2007.

Metacel timely brought suit under 35 U.S.C. § 271(e)(2)(A) pursuant to the Hatch-Waxman Act,[5] alleging that the product described in Rubicon's ANDA would infringe the '502 patent. J.A. 42–43. As relevant here, Metacel alleged that Rubicon's proposed container labeling and package insert (collectively, Rubicon's "proposed labeling") would induce downstream users, such as physicians, pharmacists, and patients, to store Rubicon's ANDA product at a temperature from about 2° to 8°C, as claimed. *Id.*

Rubicon denied Metacel's infringement allegations in its answer, J.A. 55, and noninfringement contentions, J.A. 590, 592. And following discovery, Rubicon moved for summary judgment of noninfringement. *See* J.A. 517–20 (motion); *see also* J.A. 525–68 (brief in support of motion). Rubicon argued that there was no genuine dispute of material fact that its proposed ANDA labeling would not induce infringement of the '502 patent. *See id.* at 559. In Rubicon's view, a finding of induced infringement would require a label to instruct or encourage, and not merely permit, infringement. *See id.*; *see also* J.A. 5981–82. Thus, it

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[3] One minor semantic difference is that the package insert states that the "Product" can be refrigerated, while the container label simply states that "It" (referring to the product) can be refrigerated.

[4] 21 U.S.C. § 355(j)(2)(A)(vii)(IV), (B)(i).

[5] The *Drug Price Competition and Patent Term Restoration Act of 1984*, codified at 21 U.S.C. § 355(b)(2), is referred to as the "Hatch–Waxman Act."

contended that, because its proposed labeling instructed room temperature storage, and only *optionally* mentioned refrigeration, its labeling could not induce infringement of claim 1 as a matter of law. *Id.*

Metacel opposed the motion, arguing that "at least two express statements in Rubicon's ANDA contradict Rubicon's argument." J.A. 5953. Specifically, Metacel argued that Rubicon's ANDA explained that "[t]here is no difference in [Rubicon's] storage temperature statement compare[d]" to Ozobax's label, and that Rubicon's "[s]torage [s]tatement contained in its ANDA filing also instructs" storage "at from about 2 to about 8° C." *Id.* (citation omitted). Implicit in those arguments is that the Ozobax label prescribes a storage condition that reads on claim 1 of the '502 patent.

The district court granted Rubicon's motion. It explained that "[t]he label is what matters, because that is what the downstream users—either a healthcare practitioner or patient—will rely upon." *Summary Judgment Decision*, J.A. 6017 (citing *HZNP Meds. LLC v. Actavis Lab'ys UT, Inc.*, 940 F.3d 680, 701–02 (Fed. Cir. 2019)). It therefore held that, because Rubicon's proposed labeling instructs room temperature storage and only optionally allows refrigeration, "infringement will not occur because downstream users will read and follow the label, not the ANDA paperwork." *Id.* at 6018. The district court also rejected Metacel's non-label evidence and related arguments as insufficient to create a genuine issue of material fact because Rubicon's statements to FDA are nonpublic and therefore could not induce a downstream user to infringe the '502 patent. *Id.* at 6017.

Metacel then filed a motion for reconsideration, lodging similar arguments on the merits. *See* J.A. 6023–26 (motion); *see also* J.A. 6027–47 (brief in support of motion). It also asserted, for the first time, that it was prejudiced by the district court's consideration of Rubicon's summary

judgment arguments, which were not adequately noticed or briefed in violation of the district's local patent rules. J.A. 6034–38. The district court denied Metacel's motion, adhering to its original judgment and once again rejecting Metacel's arguments regarding its non-label evidence, at least in part, because "Metacel plainly misrepresent[ed] the breadth of Rubicon's FDA submission." *Reconsideration Decision*, at *3. The district court also rejected Metacel's notice arguments because Metacel had failed to raise any such arguments in its opposition to summary judgment and could not do so for the first time in its motion for reconsideration. *Id.* at *2–3. The district court entered its final judgment accordingly. J.A. 1–3.

Metacel timely appealed, and we have jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

Metacel contends on appeal that the district court erred in granting summary judgment of no induced infringement for two principal reasons. First, Metacel argues that the district court overlooked or misinterpreted evidence that demonstrated that genuine issues of material fact remained regarding whether Rubicon's proposed labeling would induce infringement of the '502 patent's storage condition limitation. Second, Metacel argues that it was prejudiced by the district court's consideration of Rubicon's non-infringement arguments regarding the storage condition limitation on summary judgment because those arguments were not adequately noticed or briefed in violation of the district court's local patent rules and the Federal Rules of Civil Procedure.

We disagree. The district court properly granted summary judgment of no induced infringement because there is no genuine dispute that Rubicon's proposed ANDA label clearly instructs room temperature storage while only *optionally* permitting refrigeration. Metacel's nonpublic statements to FDA do not supplant Rubicon's proposed

labeling, which is directed to the public, to create a genuine issue of fact. Regardless, those statements were not presented by Metacel in their full context and, when considered fully, support Rubicon's position of no induced infringement. The district court also did not abuse its discretion in rejecting Metacel's notice arguments as belated. We will address each of Metacel's arguments in turn.

We review the grant of summary judgment de novo, according to the law of the regional circuit, which in this case is the Third Circuit. *Frolow v. Wilson Sporting Goods Co.*, 710 F.3d 1303, 1308 (Fed. Cir. 2013). Summary judgment is only appropriate if the movant "shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *see also Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). All reasonable inferences are drawn in favor of the nonmovant. *Anderson*, 477 U.S. at 255. "We apply our own law, however, with respect to patent law issues." *Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.*, 104 F.4th 1370, 1376 (Fed. Cir. 2024).

The key factor in this appeal is that it is inducement of a method claim that is at issue. The relevant statute provides that "[w]hoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). Within the "ANDA context, it is well-established that mere knowledge of possible infringement by others does not amount to inducement; specific intent and action to induce infringement must be proven." *Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2015) (internal quotation marks and citation omitted). For cases involving method of use patents, we therefore "examine whether the proposed label 'encourage[s], recommend[s], or promote[s] infringement.'" *HZNP*, 940 F.3d at 701–02 (alterations in original) (quoting *Takeda*, 785 F.3d at 631). Labels that "[m]erely describ[e] the infringing use . . . will not suffice." *Id.* at 702.

Claim 1 of the '502 patent requires that the claimed oral solution is stored "at from about 2 to about 8°C," *i.e.*, refrigerated. '502 patent col. 10 ll. 58–59. Rubicon's proposed label does not encourage refrigeration. Instead, it instructs downstream users to store the product "at 20° to 25°C," *i.e.*, room temperature. J.A. 603, 623. The proposed label's allowance of refrigeration, stating that the product "can also be stored at 2°C to 8°C," merely describes the temperature range for refrigeration *if* the downstream user chooses to refrigerate. *Id.* Stated otherwise, the label indicates that *if* a downstream user decides to refrigerate the product, despite instructions to store the product at room temperature (which is noninfringing), *then* it should store the product at temperatures from 2°C to 8°C. That is not inducement.

Rubicon's proposed labeling is similar to that at issue in *HZNP*, where the prescribing information provided a "subsequent application" warning in an "'if/then' manner: *if* the user wants to cover the treated area with clothing or apply another substance over it, *then* the patient should wait until the area is dry." *HZNP*, 940 F.3d at 702. In *HZNP*, we concluded that such a permissive statement "does not encourage infringement, particularly where the label does not require subsequent application." *Id.* The same logic applies here: because there is no genuine dispute that Rubicon's proposed labeling does not instruct refrigeration and, in fact, instructs downstream users otherwise, the proposed labeling cannot indicate a specific intent to induce downstream users. Moreover, that some such users may infringe does not help Metacel either. *See Takeda*, 785 F.3d at 631 ("The mere existence of direct infringement by physicians . . . is not sufficient for inducement.").

Metacel points to Rubicon's nonpublic communications with FDA and other testimony as circumstantial evidence to show a genuine issue of specific intent, *see* Metacel Br. 42–43, and to suggest that the label is ambiguous and

requires consideration of expert testimony, *see id.* at 37, 40, 43. We agree that, given the proper facts, circumstantial evidence may lend support to a finding of specific intent in drug label cases. *See AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010). But still, "[t]he pertinent question is whether the proposed label instructs users to perform the patented method." *Id.*; *see, e.g.*, *Grunenthal GmbH v. Alkem Lab'ys Ltd.*, 919 F.3d 1333, 1339–40 (Fed. Cir. 2019) (affirming no inducement where the label included but did "not specifically encourage" infringing application). And as we have explained, even "vague label language cannot be combined with speculation about how physicians may act to find inducement." *Takeda*, 785 F.3d at 632. Thus, where, as here, a label is unambiguous, circumstantial evidence cannot override its plain language. *See, e.g.*, *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1324 (Fed. Cir. 2012) (circumstantial evidence, including FDA materials, offered to show specific intent could not overcome the label's clear omission of any such instruction, precluding an inducement finding); *see also HZNP*, 940 F.3d at 701 (affirming grant of summary judgment of no induced infringement based only on the ANDA label).

Metacel's circumstantial evidence, even when considered, fails to create a genuine issue of material fact regarding Rubicon's specific intent to induce infringement. First, Rubicon's FDA submissions are not available to downstream users and therefore cannot cause inducement. Second, Metacel did not present those FDA submissions in their full context. For example, Metacel points to an FDA submission that states "[t]here is no difference in [Rubicon's] storage temperature statement compare[d] to [Ozobax]." Metacel Opening Br. 42. Notably, however, Metacel omitted the table provided directly beneath that statement that contains a "[j]ustification of [d]ifferences" column, wherein Rubicon explains that its proposed labeling is different from Ozobax's label (and thus different from claim 1

of the '502 patent) because its ANDA product, unlike Ozobax, could be stored at room temperature "per acceptable long term stability data." J.A. 11.

Metacel's expert testimony is also unpersuasive because it relies on downstream users turning to Metacel's own Ozobax label as evidence of Rubicon's specific intent to induce: "Metacel presented uncontested expert testimony that a pharmacist, after reading Rubicon's ANDA product label, which explicitly lists two contradictory storage conditions, would 'defer to the storage instructions for the reference listed drug (*i.e.*, Metacel's drug or the RLD).'"[6] Metacel Opening Br. 43 (quoting Metacel's expert's testimony). That is not persuasive. Metacel cites no case law or other authority to convince us otherwise.

Finally, we turn to Metacel's notice arguments. "Applying Third Circuit law, we review a district court's grant or denial of a motion for reconsideration for an abuse of discretion." *Golden Bridge Tech., Inc. v. Apple Inc.*, 758 F.3d 1362, 1367 (Fed. Cir. 2014). We see no abuse of discretion in the district court's rejection of those arguments as belated because they were raised for the first time as part of Metacel's motion for reconsideration. *See id.* at 1369 (affirming denial of reconsideration of summary judgment based on an argument raised for the first time in the motion for reconsideration); *SmartGene, Inc. v. Advanced Biological Lab'ys, SA*, 555 F. App'x 950, 954 (Fed. Cir. 2014) (affirming that arguments not in a party's summary judgment briefing were deemed forfeited on reconsideration). We therefore do not disturb the district court's judgment on that basis.

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[6] The RLD stands for Reference Listed Drug.

CONCLUSION

We have considered Metacel's remaining arguments and find them unpersuasive. For the foregoing reasons, we affirm.

AFFIRMED